

REMARKS

Claims 1-3, 8, 10-21, and 24-29 are presented for the Examiner's review and consideration. In this Response, claims 1-2, 10-12, 17-21 and 24 are amended; claim 9 has been cancelled, and claim 29 has been added. Applicant believes that the claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. No new matter has been added.

Rejection under 35 U.S.C. §112

Claim 1 was rejected under 35 U.S.C. § 112 for insufficient antecedent basis for the limitation "said anchor". Claim 1 has been amended herein, and the limitation has been removed from the claim. Accordingly, Applicant respectfully requests withdrawal of the section 112 rejection.

Rejections under 35 U.S.C. §103

Claims 1-3, 8-11 and 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams (U.S. 6,099,552) ("Adams") in view of Schwartz (U.S. 6,306,159) ("Schwartz"). Claims 12-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams and Schwartz. Claims 21 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams and Schwartz, and further in view of Ogiu (U.S. 4,235,238) ("Ogiu"). Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams and Schwartz, and further in view of Hayhurst (U.S. 4,741,330) ("Hayhurst"). Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams and Schwartz, and further in view of Egan (U.S. 6,106,545) ("Egan"). Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams, Schwartz, and Hayhurst, and further in view of Huxel (U.S. 6,503,259) ("Huxel").

Adams

Adams discloses medical devices which include a clip having a stem, an anchor at a first end of the stem and a bolster at or near a second end of the stem. (Abstract). With reference to Fig. 1 of Adams, medical device 100 includes a stem 101 having first end 102 and second end

103. Stem 101 has at least one transverse hole 104 therein of any suitable shape (e.g. circular rectangular, square, etc.). (Col. 2, lns. 37-38). Stem 101 is further characterized by an anchor 105 at its first end 102. (Id). Anchor 105 comprises at least one anchor member that extends away from stem 101 and towards second end 103. (Id). Medical device 100 also comprises a bolster 106, which includes a flap 107 adapted to be inserted into hole 104. (Id).

Bolster 106 is made from a material, however, that is rigid enough so that, when in use, flap 107 remains in a selected hole 104 to apply pressure against a GI wall. (Col. 2, lns. 54-57).

The rejection states that Adams discloses a plurality of passages 104 which allow for the threading of a suture. Applicant respectfully disagrees. Holes 104 are provided to trap a flexible flap, to lock a bolster at a position along a stem. There is no suggestion in Adams that this is a through hole which would allow threading a suture. In fact, a through hole would not be necessary to accomplish the objective of Adams, and would weaken the stem. Nowhere in Adams is it suggested that a suture, or anything like a suture, is to be used with the device of Adams, or could be used with the device. The rejection therefore improperly reads into Adams a disclosure that is clearly not present.

In addition, independent claims 1 and 9 have been amended herein to specifically recite “said first passage located in close abutting proximity to said second end, whereby a suture threaded through said first passage may be pulled to thereby rotate the implant and move said second end in the pulling direction, said abutting location providing improved rotational leverage as compared to a location more distal to said second end”. Clearly Adams does not disclose a through hole near an end, and the amended claim language clarifies why this is advantageous.

It should also be noted that Adams does not disclose or suggest rotation of the device of Adams. Further, rotation of Adams would be counter to the purpose of Adams, which is to pierce the tissues and anchor the stem with a barbed end, where the stem **must remain in the original orientation** so that the bolster may be applied, thereby binding the tissue. Accordingly combining Adams with Schwartz would not be logical or workable, and is therefore neither suggested or obvious.

Schwartz

In Schwartz, an outer wall anchor is placed within a cannulated needle. (Col. 2, lns. 9-10). A needle is then inserted through the meniscus, and a push rod deploys the outer wall anchor outside of the meniscus. (Id). With tension on the suture, the outer wall anchor flips into place, providing support against the outer rim wall of the meniscus. (Id).

With reference to Fig. 2 of Schwartz, hole 24b is located off-center. (Col. 4, lns. 27-28). This off-center placement promotes pulley action.

Thus, Schwartz uses a needle to form an opening in body tissue, not the outer wall anchor. Indeed, as can be seen in Fig. 2a of Schwartz, even a square ended anchor can be used in Schwartz. Further, while Schwartz discloses an advantage to an offset hole, Schwartz fails to disclose or suggest a hole adjacent a pointed end, and thus the combined advantages of an improved leverage with respect to a leverage point merely “off-center”, and a reversing of the device so that it does not reenter the body tissue opening or passage. The need to promote a reversing does not exist and is therefore not addressed in Schwartz, because there is a push rod and cannulated needle occupying the passage through the body tissue, and thus the outer wall anchor cannot reenter the passage.

In summary, Adams does not disclose an anchor that is rotated after passing through body tissue, and in fact, teaches against same. Further, Adams does not disclose a through-hole, or passing a suture through a hole in a device. Schwartz does not disclose an anchor that is used to pierce body tissue, and must be used with a cannulated needle. Schwartz further does not disclose a suture passing through a hole near an end of the device, and therefore does not offer an improved leverage, and further does not promote a movement of an opposite end away from reentry into a tissue passage.

In contrast, with reference to the figures of the present invention, and particularly Fig. 1, it can be seen that one passage is located adjacent to a pointed end of the device. As stated in the specification at paragraph [0033], “The passage 30 is formed entirely in the body section 22. However, the passage 32 is formed partially in the body section 22 and partially in the pointed end portion 34. Thus, the major portion of the passage 32 is formed in the body portion 22. However, a minor portion of the passage 32 extends into the pointed end portion 24.”

Once the anchor 158 has been moved through the layers 150 and 152 of body tissue, the section 166 of the suture 162 is tensioned. (§[0102]). The anchor 158 and the layers 150 and 152 of body tissue apply sufficient friction against the section 170 of the suture 162 that tensioning the section 166 of the suture is effective to apply a torque to the anchor which rotates it from the orientation illustrated in FIG. 7 to the orientation illustrated in FIG. 8. (Id).

Thus, the present invention functions better than the prior art because (a) an initial puncturing step with a separate device is not needed, (b) while a push rod may be used, it is not always required, (c) leverage is improved, while simultaneously promoting a reversing or backwards movement of the device so that a trailing end does not reenter a passage in body tissue.

As can be seen in the figures, and understood from the specification, it is clearly an inherent property of the device that applying a pulling force close to a distal end of the device will cause a displacement of the proximal end away from a starting location upon rotation. The proximal displacement would taper off considerably as force is applied closer to the center of the device. The prior art clearly does not disclose or suggest this important distinction.

New claim 29, replacing independent claim 9 for clarity, adds the additional elements, with respect to amended claim 1, of threading a suture through said first passage prior to piercing body tissue, and promoting movement of said first end in a direction away from the opening in body tissue.

The foregoing arguments apply equally to remaining independent claims 21 and 24. Each claim recites a passage extending **through** the implant body, with a suture section threaded through this passage. As stated above, this element is missing in Adams, and further, Adams cannot be combined with Schwartz because the device of Adams cannot be rotated after insertion. What remains is the disclosure of Schwartz which fails to show, at least, a body tissue piercing pointed or conical end, and a through hole in close abutting proximity to said end.

With respect to claim 21, Applicant respectfully submits that Ogiu does not show a passage in the body of the implant close to the end. In Fig. 51, referred to in the rejection, there is a passage in an insertion tool close to the end of the tool, but this does not apply to the implant, and is thus not germane to the claim. Accordingly, Ogiu does not remedy the deficiencies of Adams and Schwartz with respect to claim 21.

With respect to claim 24, the applicability of Hayhurst with respect to the slidability of the suture is moot, as the remaining claim elements are not disclosed in Adams and Schwartz, as described above. Moreover, Hayhurst is directed to a resiliently expanding anchor, and not a rotating anchor, and is thus non-analogous art.

Accordingly, Applicant respectfully submits that independent claims 1, 21, 24 and 29 (replacing claim 9) are patentable over Adams in view of Schwartz. As claims 2, 3, 8 and 27 depend from claim 1, claims 25-26 and 28 depend from claim 24, and claims 10-20 depend from claim 29, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited art for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejections.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Applicant respectfully submits, should the Examiner agree that Adams was incorrectly characterized as disclosing a passage allowing for threading a suture, that any subsequent Office Action should not be final, as Applicant would then not have had a full and fair opportunity to request and receive reconsideration.

A fee for a one month extension is believed to be due, and is submitted herewith via credit card. However, please charge any other required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-003-1).

Respectfully submitted,

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